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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,509	02/12/2001	Eugene Lukanidin	12754A	6832

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	7

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,509	LUKANIDIN ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-8 and 10-25* is/are pending in the application.

4a) Of the above claim(s) *14-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-8 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that restriction is appropriate only when the claimed inventions are independent and distinct. Applicant argues that the different groups are related and further argues that they are aspects of a single invention. Applicant additionally states that evidence that the groups are patentably distinct must be provided if the restriction requirement is made final.

Applicant's arguments have been fully considered but have not been found to be persuasive.

MPEP §802 states as follows:

802.01 Meaning of "Independent" and "Distinct"
35 U.S.C. 121 quoted in the preceding section states that the Commissioner may require restriction if two or more "independent and distinct" inventions are claimed in one application. In 37 CFR 1.141, the statement is made that two or more "independent and distinct inventions" may not be claimed in one application.
This raises the question of the subjects as between which the Commissioner may require restriction. This, in turn, depends on the construction of the expression "independent and distinct" inventions.
"Independent", of course, means not dependent. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the codification of the patent laws indicate that 35 U.S.C. 121: "enacts as law existing practice with respect to division, at the same time introducing a number of changes." The report on the hearings does not mention as a change that is introduced, the subjects between which the Commissioner may properly require division.
The term "independent" as already pointed out, means not dependent. A large number of subjects between which, prior to the 1952 Act, division had been proper, are dependent subjects, such as, for example, combination and a subcombination thereof; as process and apparatus used in the practice of the process; as composition and the process in which the composition is used; as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word "independent" would clearly have been used alone. If the Commissioner has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions,

e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term "distinct" with the term "independent", indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact,"distinct" inventions, even though dependent.

MPEP § 803 states,

803 Restriction - When Proper
Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)).

CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS
There are two criteria for a proper requirement for restriction between patentably distinct inventions:
(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).
Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.

For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant.

Applicant's comments with respect to the expense of prosecution and double patenting issues are noted. Regardless, what is required for restriction is that the different inventions be independent or distinct. Evidence of the distinctness of the separate inventions was provided in the office action of paper no. 5. These groups represent different inventions and require different, non-contiguous searches, as evidenced by their different classification. Thus to consider all of these groups would constitute an undue burden.

Groups I and II are related as product and process of use. Applicants are advised that at such time as the elected product claim(s) are indicated as being allowable, rejoinder of claims drawn to methods of using such may be requested under 35 U.S.C. §103(b) pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). Such rejoinder is *not* tantamount to a withdrawal of the restriction requirement.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 4-6, 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 5801142 (Zain et al., September 1, 1998). Zain et al. teaches the mts-1 protein of the instant claims. That the protein forms a trimer is an inherent property of the protein; Applicant's discovery of this property does not render the trimer novel. Since the tendency to form multimers is a result of the structure of the mts-1 protein, the protein of the '182 patent would exist in multimeric forms, regardless of whether this property was recognized at the time. See MPEP § 2112. Pharmaceutical compositions are taught in column 18, lines 45-46 and 60-67, columns 19 and 20, and column 21, lines 1-16, of the '142 patent.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '142 patent in view of U.S. patent 6167888 (Tuszynski et al., 2001, priority date June 1997).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The '142 patent teaches as set forth above and further teaches that the mts-1 can be used to promote cell growth (column 18, line 64) and teaches that it is closely related to a gene involved in cell growth. The '142 patent further teaches that the mts-1 protein may be useful for stimulating nerve cells to grow (column 18, lines 55-59). The '142 patent fails to teach neurotrophic factors or coadministration of such factors with mts-1. The '888 patent teaches that bFGF, NGF, CNTF, BDNF, NT3, NT4, and IGF-I are neurotrophic factors and further teaches that some of these stimulate growth of nerve cells (column 3, lines 65-67 and column 4, lines 1-10). The '888 patent also teaches that such factors can be used to treat spinal cord injury (see the whole document). The '888 patent fails to teach administration of mts-1 with these factors. However, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of the '142 patent with the '888 patent to coadminister mts-1 with a neurotrophin.

One of ordinary skill would have been motivated to do so because the '888 patent teaches that factors that promote nerve cell growth are useful to treat spinal cord injury. Thus, one of ordinary skill would expect that a combination of factors having such properties would also be useful. *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4-8 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to multimers of Mts-1 proteins. Such derivatives would include any and all proteins that could be described as "Mts-1 proteins". However, Applicant has described only two Mts-1 proteins. There is no description of the required structural features of Mts-1 proteins, or of the conserved regions that would be critical for function. There is thus no way to determine what other proteins would be identifiable as "Mts-1" proteins; there are no distinguishing characteristics set forth in the specification. Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude

that applicant was in possession of the genus of proteins that could be described as "Mts-1 proteins" and thus of multimers thereof.

Claim 6 is drawn to "wild-type" mts-1 proteins. Applicant has described one such protein, but has not set forth the characteristics of wild-type proteins so that one of skill in the art could recognize others. Wild-type proteins already exist in nature and have particular sequences; there is no way to identify such species without explicit disclosure of their precise sequences.

8. Claims 4-8 and 10-13 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mouse and human Mts-1 proteins, does not reasonably provide enablement for any and all variants to any and all Mts-1 proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has described two Mts-1 proteins and two mutants, del-75 and 4S. However, applicant has not described the characteristics of the Mts-1 proteins so that one of skill in the art could predictably identify other such proteins identifiable as "Mts-1" proteins. Applicant has not described the properties or characteristics that are required for a functional protein. Thus, the essential characteristics of Mts-1 proteins are not described, and one of skill in the art would not be able to predict what other proteins would have these characteristics. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in Mts-1 function, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4-8 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a protein identified only as "mts-1". The use of this term is indefinite because it only describes a protein or nucleic acid of interest by an arbitrary name. The claims should refer to a sequence presented in the sequence listing. While the name itself may have some notion of the activity of the protein, there is nothing in the claim that distinctly identifies the protein. Others in the field may isolate the same protein and give it an entirely different name or give the same name to a different protein. Describing biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly identify what the protein is.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
October 15, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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